

**§ 106-65.49. Article not applicable in certain cases.**

The provisions of this Article and/or regulations promulgated hereunder shall not apply to:

- (1) Any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license issued pursuant to section 351 of the Public Health Service Act (42 U.S.C. section 262) and regulations promulgated thereunder;
- (2) Any finished virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product or other biological product shipped prior to licensing for development or investigational purposes in compliance with the requirements of the Federal Food, Drug and Cosmetic Act (21 U.S.C. section 301 et seq.) or the Animal Virus, Serum, and Toxin Law of March 4, 1913 (37 Stat. 832; 21 U.S.C. section 151 et seq.), and rules and regulations promulgated thereunder; and
- (3) Any etiological agent shipped in accordance with regulations promulgated under section 361 of the Public Health Service Act (42 U.S.C. section 264). (1973, c. 1091.)